

RESPONSE TO REQUIREMENT FOR RESTRICTION AND ELECTION OF SPECIES

This action requires restriction under 35 U.S.C. 121 among Groups I – XIV. Applicants respectfully elect, with traverse, Group II, (Claims 125-144 drawn to compounds of Formula (I) wherein the cyclic nitrogen-containing moiety is indole, R1 is alkyl or benzyl, and R2 is diazine. For search purposes, Applicants elect Example 3B, 5-{3-[(2,4-Bis-trifluoromethyl-benzyl)-(5-ethyl-pyrimidin-2-yl)-amino]-propoxy}-1-methyl-indol-3-yl)-acetic acid, shown on page 82 of the specification and as the third compound in Table 3. Claims 125-144 read on the elected species. Applicants reserve the right to file divisional applications on the subject matter not elected under this response.

Applicants respectfully traverse the examiner's requirement for the restriction as laid out between Groups I – XIV, on multiple grounds.

First, the restriction requirement is traversed because the examiner has not met his burden in showing that such a restriction is necessary. 35 USC 121 holds that restriction may be required where independent and distinct inventions are claimed. MPEP 803 clarifies that restriction may be required when inventions are either independent (as defined in MPEP 806.06) or distinct (as discussed in MPEP 805.05), and MPEP 808 Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention as claimed is either independent or distinct from the other(s); and (B) the reasons why there would be a serious burden on the examiner if restriction is not required, i.e.. the reasons for insisting upon restriction there between as set forth in the following sections.” MPEP 808.01 elaborates, “The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given.”

The examiner has not met his burden with respect to aspect (A) above. The requirement for restriction alleges that the inventions as divided into Groups I-XIV do not relate to a single inventive concept. MPEP 803.02 holds that “unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.” In re Harnisch. 631 F.2d 716. 206 USPQ 300 (CCPA 1980); and Ex parte Hozurni, 3 USPQ2d 1059 (BPAI 1984). Substantial chemical features in common are evidenced by Formula I and the Examples shown on pages 75-88 and in Table 3. The fact that a certain amount of variability exists within each of Markush groups R₁-R₄ does not render the claimed subject matter unrelated; nor does the fact that different embodiments of R₁-R₄ may be combined to form different species. Furthermore, the compounds feature a common utility of

mediating disease by modulation of peroxisome proliferator activated receptors (PPARs), see for example pages 1-3 of the specification for a very brief introduction to PPAR biology; 52-55 of the specification regarding biological assays and target diseases to be treated; and pages 88-93 of the specification showing data from the biological assay.

Further, the examiner has not met his burden with respect to part (B) above in showing that a serious search burden would ensue if restriction were not imposed. The examiner has given no reasons why he would face a serious burden if restriction were not required. On this ground alone, restriction is improper and it is respectfully requested that its requirement be withdrawn.

Second, the restriction requirement is traversed since it is directed, in part, to subject matter contained within individual Markush claims. 35 USC 121 does not permit imposition of a restriction requirement of subject matter contained within a single Markush claim. No statutory or legal authority exists for imposing a restriction requirement on a claim which effectively fractionates it into the various subparts as has been required by the examiner. In re Weber 198 USPQ 328 (CCPA 1978) and In re Watkinson 14 U.S.P.Q. 2d 1407(Fed. Cir. 1990). M.P.E.P 803.02 advises the examiner that he should examine the Markush claim unless the subject matter in the claims lacks unity of invention. The presently claimed invention has unity of invention. The compounds of the present invention share a substantial chemical feature and a common utility as discussed above.

Cited in the restriction requirement are a number of PCT rules regarding unity of invention which conclude with the identification of a reference from the International Search Report of the Rice reference, which, it is alleged, features compounds read upon by the instant application. Applicants respectfully traverse the application of this reference, due to the ambiguous placement of ethyl groups in the species featuring as R' the group 3-diethylaminopropyl, and the like. The reference is unclear whether "diethyl" groups in 3-diethylaminopropyl are N-linked, or substituted at the 3-carbon of the propyl chain, and therefore the cited species is not properly applicable under PCT Rule 13.2 Annex B Part 1(f)v. In any case, the present Preliminary Amendment has been structured to remove this issue.

Remarks

Applicants wish to thank the Examiner for noting the improper recitation of dependency in claims 126-144. The present Preliminary Amendment should correct this issue. As noted above, the claims have also been amended to avoid any perceived overlap with compounds disclosed in the Rice reference, by requiring that at least one of R₁ and R₂ is not methyl or ethyl.

In light of the above, the requirement for restriction under 35 U.S.C. 121 is improper and should be withdrawn. It is respectfully submitted that the claims are in condition for allowance. Notification to this effect is earnestly solicited. The Examiner is encouraged to contact the Applicants' undersigned agent to discuss this matter if any questions should arise upon further examination of the pending claims.

Respectfully submitted,

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Date

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